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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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November 28, 2001

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION: DOCKET 75N-183H

Dear Sir or Madam:

This Citizen Petition is submitted under 21 CFR Sec. 10.30 on behalf of The Soap and Detergent Association and The Cosmetic, Toiletry, and Fragrance Association Coalition (the "Industry Coalition" or "Petitioner"). This Citizen Petition requests the Commissioner of Food and Drugs to take the following action with respect to the OTC Topical Antimicrobial Drug Products Review, including the Tentative Final Monograph for OTC Health Care Antiseptic Drug Products, 21 CFR Part 333, Subpart E (the "TFM").

ACTION REQUESTED

The Petitioner requests the Commissioner to reopen the administrative record of the TFM solely for the purpose of including the attached information relating to finished product test methodology in developing the final OTC drug monograph for healthcare antiseptic drug products and in future deliberations regarding a Final Monograph for other categories of topical antimicrobial products.

STATEMENT OF GROUNDS

The time specified for comment on the TFM, published June 17, 1994, has lapsed. *See* 21 CFR Sec. 330.10 (a)(7)(iii). The Agency's regulations recognize, however, that the administrative record of a tentative final monograph may be reopened to consider new data and information, see 21 CFR Sec. 330.10 (a)(10)(iii), and that new data and information may be considered by the Commissioner prior to issuing a final monograph for good cause shown. 21 CFR

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Sec. 330.10 (a)(7)(v). The Petitioner has made a number of submissions to FDA providing data and comment pertinent to this rulemaking, including comments regarding the efficacy testing for finished product proposed in the TFM. An Industry Coalition Proposal for Finished Product Efficacy Testing of Health Care Antiseptic Drug Products was submitted September 29, 1999 in advance of a public feedback meeting held November 3, 1999 to discuss the issue of finished product efficacy testing.

The attached materials have been provided in response to specific information requested by the Agency at the November 1999 feedback meeting. Time kill kinetic studies and the results of a study on the effect of neutralization in surrogate endpoint testing were identified as two areas requiring additional input from the Industry Coalition. Although the Agency has not yet issued a Feedback Letter, Petitioner submits this data for Agency consideration because FDA has stated it is currently developing a Monograph that will cover three of the six product categories proposed in the Health-Care Continuum Model (HCCM) and data relating to finished product testing underpin all product categories in the HCCM.

It is important to note that this Petition is not typical of other Citizen Petitions received by the Agency. We are not asking FDA to adopt any significant new policies by this Petition. Instead, we are asking the Agency to consider this material that is directly relevant to actions previously discussed and has been requested of the Petitioner by FDA. Good cause exists for the Commissioner to consider this material as it is responsive to questions raised by FDA during public meetings since the close of the record more than six years ago.

ENVIRONMENTAL IMPACT

According to 21 CFR Sec. 25.31(c), this Petition qualifies for a categorical exclusion from the requirement that an environmental assessment be submitted.

ECONOMIC IMPACT

According to 21 CFR Sec 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of this Petition.

CERTIFICATION

The undersigned certify that, to the best of their knowledge and belief, this Petition includes all information and views on which the Petition relies, and that it includes representative data known to the Petitioner which are unfavorable to the Petition.

Respectfully submitted,

Richard I. Sedlak
Vice President of Technical and International Affairs
Soap and Detergent Association

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association

cc: Charles J. Ganley, M.D. (HFD-560)
Ms. Debbie L. Lumpkins (HFD-560)

Evaluation of Health Care Antiseptic Drug Products by *In Vitro* and *In Vivo* Surrogate End-Point Test Methods

November 28, 2001

Prepared by
The Soap and Detergent Association and
The Cosmetic, Toiletry, and Fragrance Association
Industry Coalition

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EN 1040, EN 1499, and EN 1276

Tab 7 American Society for Testing and Materials (ASTM) Methods:
ASTM E 1054-91, ASTM E 1115-91, ASTM E 1173-93, ASTM E 1174-00, ASTM E 1174-87

Tab 8 Appendices D and E, from SDA/CTFA Industry Coalition Citizen Petition August 6, 2001

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Volume II

CTFA/SDA Proposal for Finished Product Efficacy Testing of Health Care Antiseptic Drug Products September 29, 1999

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